

Atty. Dkt. No. 078853-0304

REMARKS

The invention relates to methods for preventing or treating cardiovascular disease comprising administering an agent that binds to sphingolipid or a sphingolipid metabolite or receptors thereof. Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Prior to the present submission, claims 1-20 were pending in the application.

Applicant has amended claims 1 and 13 herein. Basis for "patient" can be found in the application, for example, at pages 8 lines 2-5. Basis for "effective amount" can be found in the application, for example, at pages 91 lines 6-9. Accordingly, the amendments raise no issue of new matter. These amendments also do not alter the scope of the claims.

35 U.S.C. § 112, second paragraph

Applicant respectfully traverses the rejection of claims 1-20 as allegedly being indefinite under 35 U.S.C. § 112, second paragraph, for allegedly failing to recite essential elements of the claims. Applicant has amended the claims to specify a suitable host (i.e., a patient). Thus, this ground for rejection has been obviated. Applicant also has amended the claims to specify administration of an "effective amount" of the agent. Thus, this additional ground for rejection has also been obviated. Applicant respectfully traverses the remaining ground for rejection -- the requirement for the claim to recite a suitable mode of administration.

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). Recognizing that the English language is not always precise, the settled law has established that the essential inquiry in a definiteness analysis is whether the claims set out and circumscribe the claimed subject matter with reasonable particularity. *See, e.g.*, MPEP § 2173.02; *see also*, *Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112

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demands no more.") (emphasis added). Definiteness is not analyzed in a vacuum, but in light of the content of the specification, and with the knowledge available to the skilled artisan.

Applicant respectfully disagrees with Examiner that the claims are indefinite because they do not specify a suitable mode of administration. It is well known in the art that agents may be administered to a patient by any of various modes including oral, pulmonary, and parenteral administration. For example, the specification describes administration of pharmaceutical compositions by "intramuscular, intrathecal, epidural, intraperitoneal or subcutaneous injection" on page 93 lines 20-21, and describes "oral, nasal, buccal, ocular, dermal, rectal or vaginal delivery" of therapeutic agents on page 94 lines 27-28. Applicant respectfully submits that, when read in light of the specification, the skilled artisan is reasonably apprised of the meaning of "administering" without the need to specify a particular mode.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

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